



DEPARTMENT OF HEALTH AND HUMAN SERVICE

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Public Health Service

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Food and Drug Administration
New Orleans District
Southeast Region
4298 Elysian Fields Ave.
New Orleans, LA 70122

Telephone: 504-589-6341
FAX: 504-589-6360

April 14, 1999

WARNING LETTER NO. 99-NOL-19

OVERNIGHT DELIVERY
FEDERAL EXPRESS

Mr. Tracy J. Defelice, Owner
Defelice Marina and Seafood
163 Old Bridge Road
Dulac, Louisiana 70353-2009

Dear Mr. Defelice:

On February 3, 1999, investigators of the Food and Drug Administration (FDA) conducted an inspection of your crab and shrimp dock, located at 163 Old Bridge Road, Dulac, Louisiana. The investigators documented that your firm was not in compliance with FDA's seafood processing regulations and the Good Manufacturing Practices requirements for foods. This causes your finished product, frozen peeled shrimp, to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act, in that you failed to operate in accordance with the requirements of Title 21, *Code of Federal Regulations*, (CFR) Part 123, and the Current Good Manufacturing Practice (CGMP) regulations for foods (21 CFR 110).

The seafood processing regulations, which became effective on December 18, 1997, require that you implement a preventative system of food safety controls known as Hazard Analysis Critical Control Points (HACCP). HACCP essentially involves: (1) identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products; and (2) having controls at "critical control points" in the processing operation to eliminate or minimize the likelihood that the identified hazards will occur. These are the kinds of measures that prudent processors already take. HACCP provides a systematic way of taking those measures that demonstrates to us, to your customers, and to consumers, that you are routinely practicing food safety by design. Seafood processors that have been fully operating HACCP systems advise us that they benefit from it in several ways, including having a more safety oriented workforce, having less product waste, and having fewer problems generally.

During the inspection of your processing plant, FDA investigators observed shortcomings in your system that were identical to those pointed out in the March 10 and 12, 1998, inspection and stated in the untitled letter sent to your firm on July 14, 1998. The subsequent inspection on February 3, 1999, also revealed the same deficiencies. The FDA investigator also provided you with a copy of the Domestic Seafood HACCP Report (form FDA 3501) and the FDA 483, which presents his/her

evaluation of your firm's performance regarding various aspects of the HACCP and CGMP requirements. The observation of concern to us is as follows:

- Failure to have and implement a HACCP Plan for potential hazards associated with shrimp and live crabs, as required by 21 CFR 123.6(b).

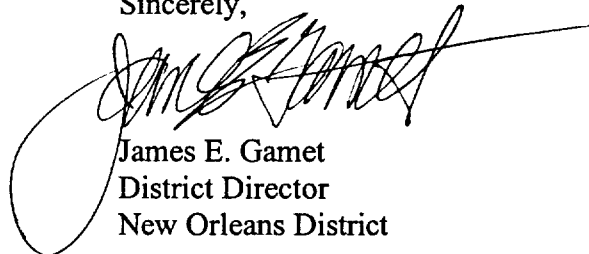
As the owner, it is your responsibility to assure that your processing plant is operating in compliance with the applicable laws and regulations. It is also your responsibility to assure not only that the current objectionable condition is corrected, but that adequate policies and procedures are implemented to prevent a recurrence of the problems.

The above identification of the violation is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice regulations. You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. This may include seizure and/or injunction.

You should notify this office in writing, within 15 working days of receipt of this letter, of the steps taken to correct the noted violations, including an explanation of each step taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for this delay and the time within which the corrections will be completed.

Your response should be directed to Patricia K. Schafer, Compliance Officer, U.S. Food and Drug Administration, 4298 Elysian Fields Avenue, New Orleans, Louisiana 70122-3896, telephone number (504) 589-7166. Should you have any questions concerning the contents of this letter, or if you desire a meeting with the agency staff, do not hesitate to contact Ms. Schafer.

Sincerely,



James E. Gamet
District Director
New Orleans District